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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,653	08/05/2003	Jan Carlsson	1614-0261P	5460

7590

06/20/2006

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,653

Applicant(s)

CARLSSON ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/673,882.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite with respect to the use of unconventional claim language; "characterized in" should be replaced with --comprising-- or --consisting of-- for clarity.

Claim 1 is also confusing with respect to the use of parenthetical subject matter. The use of parentheses to describe claim limitations is indefinite because it is unclear if the parenthetical materials are part of the claimed invention.

Claim 1 is vague and indefinite with respect to the recitation of, for example "...which zone exhibits a structure" because it is unclear if this "structure" is an inherent part of the zone and is exhibited by the zone as a matter of course. It is recommended that "exhibits" be replaced with more convention claim terminology such as --containing--. As stated above, the parenthetical material is confusing, thus, a "structure" is vague because it is unclear if this "structure" is a biological material or a mechanical material. Furthermore, it is unclear if how the "structure" and the capturer in the detection are related to each other because it appears as though they both bind to the analyte.

Art Unit: 1641

Claim 1 is further unclear with respect to part (A) where a flow matrix is recited as having "one and the same transport flow". It is unclear what this means.

The "optional" material has not been given patentable weight.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Doshi et al (US Patent No. 5,766,552).

Art Unit: 1641

Doshi et al disclose a method and device for analyzing a blood sample comprising an application zone, an enzyme pad (labeled zone) and through the remainder zones of the test device and finally contacts the measurement zone. The measurement zone is coated or impregnated with an indicator material that reacts with the enzyme-reacted sample to give an indication of the presence or amount of analyte in the sample (column 16, lines 8-27 and figure 3). It can clearly be seen in figure 3 that the measurement (detection) zone is located downstream of the absorbent and enzyme pad and the flow into and out the detection zone is a lateral flow.

Doshi discloses a device incorporating the blood separation means in which whole blood is introduced to the device through an absorbent pad (i.e. SZ) which is impregnated with a mixture of a lectin and beads of acrolein coated with lectins. RBC in the sample agglutinates upon contact with the agglutinin in the absorbent pad and is retained. Blood that is substantially free of RBC flows into a secondary separation pad and is further filtered. The sample then flows to the enzyme pad and through the remainder zones of the test device and finally contacts the measurement zone (i.e. DZ). The measurement zone is coated or impregnated with an indicator material that reacts with the enzyme-reacted sample to give an indication of the presence or amount of analyte in the sample (column 16, lines 8-27; and figure 3). It can clearly be seen in figure 3 that the measurement zone (i.e. DZ) is located downstream of the absorbent and enzyme

Art Unit: 1641

pad and the flow into and out the detection zone is a lateral flow. Doshi is seen to anticipate the claimed test kit because the test kit has nothing more than a device which is taught by Doshi.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lonnerberg et al (WO 96/22532).

Lonnerberg discloses a device comprising an application zone (Z3), a detection zone (Z1), and a transport zone (Z2) therebetween. See figure 1. Lonnerberg does not specifically teach that transport zone exhibits a structure to the analyte; however, Lonnerberg anticipates that instant claims because it is unclear if this "structure" is a biological material or a mechanical material as explained above.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fitzpatrick et al (US 5,451,504).

Fitzpatrick discloses a device comprising an application zone, a mobilization zone, a trap zone, a detection zone and an absorbent zone. See figure 1. The mobilization zone comprises labeled receptor for the analyte; the trap zone comprising immobilized ligand that will bind either free receptor or excess analyte. The detection zone comprises immobilized capture reagent for the analyte-labeled receptor complex. See column 4, lines 50-58; column 6, lines

Art Unit: 1641

38-44; column 7, lines 15-24, and column 8, lines 13-41. Fitzpatrick is seen to anticipate the claimed test kit because the test kit has nothing more than a device which is taught by Fitzpatrick.


Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
6/2/06